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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/724,135 | 11/28/00 | MCFARLAND | E 2727.1001-00 |

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EXAMINER

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| MCRAAAL | T |
| ART UNIT | PAPER NUMBER |

1641 5
DATE MAILED:
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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|------------------------------|------------------------------------|-------------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/724,135 | MCFARLAND, EILEEN LOUISE RICE |
| | Examiner Terri L. Ivory - McCaa | Art Unit 1641 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims 1-11 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) Interview Summary (PTO-413) Paper No(s) _____
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10, drawn to a method for diagnosing and a kit for the predisposition to psychosis in a progeny, classified in class 436, subclass 547.
 - II. Claim 11, drawn to a method for diagnosing or aiding in the diagnosis of a predisposition to a psychotic disorder classified in class 436, subclass 507.
2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods. Group I is a method and kit for diagnosing a predisposition to psychosis in progeny while group II is a method for diagnosing or aiding in the diagnosis of a predisposition to psychotic disorder in an individual. Each method has different function and different effect therefore group I and group II are patentably distinct.

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3. Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group, and these inventions are distinct for reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Alice O'Carroll on April 12 2001 a provisional election was made with traverse to prosecute the invention of group I, claims 1-10. Affirmation of this election must be made by applicant in replying to this Office action. Claim 11 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1- 9 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

(1) The nature of the invention – The invention is directed toward methods of diagnosing and screening for a predisposition to psychosis in a progeny who possesses Cw blood antigen. Specifically it is directed to detecting the presence of anti-Cw antibody in a biological sample from the mother of the progeny and relating the presence of said antibody to predisposition if the progeny to psychosis.

(2) The state of the prior art – The prior art, Bowman et al (Vox Sang 1993;64:226-230), discloses that women who were positive for the anti - Cw antibody had births in which the infants were healthy, still born, or had hemolytic disease. Mouro et al (The Journal of American Society of Hematology Vol. 86, No. 3 Aug. 1995), teaches that anti-

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Cw antibodies found in the mother causes hemolytic disease in the infant. Neither reference teaches a correlation between detection of anti Cw antibody in the mother to a predisposition of psychosis in the progeny.

(3) The predictability or lack thereof in the art – As indicated by the cited prior art, anti-Cw antibody, has not been definitively linked to one specific disease or has a particular amount been shown to be indicative of one disease over another in progeny nor has it been possible to identify any one particular disease such as schizophrenia, axis I disorder and axis II disorder, as indicated in the instant claims by the detection in maternal biological sample, anti Cw antibody.

(4) The Amount of Direction or Guidance present – Appropriate guidance is provided in the specification to screen for the presence of the anti Cw antibody in the maternal biological fluid, however, no guidance is available to teach a skilled artisan how to relate the presence of Cw – antibodies to psychotic disorders such as schizophrenia, axis I disorder or axis II disorder in the progeny.

(5) The presence or absence of working examples – The only example provided is insufficient. The case study displays the mother as positive for anti – Cw antibody, the father is positive for the antigen and his siblings display psychosis. The progeny is positive for the Cw antigen but there is no other evidence to support that the detection of anti Cw antibody in the mother correlates with a predisposition of psychosis in the

progeny. Therefore, the specification does not adequately disclose the detection of anti Cw antibody in maternal biological sample and relating it to the predisposition of psychosis in the progeny.

- (6) The quantity of experimentation necessary – It would require undue experimentation for a skilled artisan to make and use the invention as claimed.
- (7) The relative skill of those in the art – The level of skill in the art is high
- (8) The breadth of the claims – The instant claim is directed toward a method for diagnosing and screening for a predisposition to psychosis in a progeny who possesses Cw blood antigen.

Detection of anti Cw antibodies in a maternal biological sample may be a screening for hemolytic disease in infants as shown in Bowman et al but there is no evidence to support that the presence of the antibody would indicate potential psychotic episodes in progeny. Even the specification does not adequately support that the progeny, that inherited the Cw antigen, would be predisposed to psychosis (page 8). Psychosis is a complex disorder involving many factors such as genetic, environmental and organic brain diseases, etc. Therefore, the conclusion that carriers of CW antigen are predisposed to psychosis has not been fully supported by the specification as filed.

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7. In view of the teachings of *In re Wands*, 8 USPQ2d 1400, It has been set forth above that (1) the experimentation required to diagnose and screen for a predisposition to psychosis would be great as (2) the prior art is silent with respect to screening methods and the detection of maternal anti Cw antibodies and relating it to psychosis, (3) there are no proper guidance for how to relate the detection of anti Cw antibodies in a maternal sample to predisposition of psychosis in the progeny in the instant specification, (4) the nature of the invention is a correlation of the presence of the anti Cw antibody in the maternal biological sample to the predisposition of psychosis in a progeny, (5) the relative skill in the art is high, (6) the state of the prior art has shown to be unpredictable as evidenced by Mouro et al and Bowman described above, (7) the claims broadly recite a method to identify the predisposition of psychosis in progeny by detecting anti Cw antibody in maternal biological sample without specifically stating how this can be done without undue experimentation.

Therefore, it is maintained that one of skill in the art could not make and use the invention as claimed without undue experimentation.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 1 and 6 are vague. The recitation of "anti Cw antibody" is not clear. Is the antibody to Cw antibody being detected or are antibodies to the Cw antigen being detected?

10. Claim 10 is vague. It is not clear whether the detector for the anti-Cw antibody is another antibody comprising a label or is it a label reagent used to combine with the anti-Cw antibody for detection purposes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thorpe et al (Vox Sang 1997; 73; 174-181) in view of Foster et al U.S.Patent 4444879.

Thorpe teaches producing human monoclonal IgG antibodies specific for the Cw antigen (page 175). Thorpe does not teach a kit.

Foster teaches a kit useful for enzyme immunoassays. The kit comprises substrate, containers, enzyme labeled antibodies, pipettes, developer, controls and instructions to carry out the method of the invention (Col. 15, Lines 12 – 34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate into the method of Thorpe a kit comprising all the reagents, substrate, controls etc for the method as taught by Foster because kits are known in the art for their efficiency and economy.

Conclusion

11. Claims 1-10 are not allowed.
12. The prior art of record and not relied upon is considered pertinent to applicants disclosure.
 - (a) Coombs et al; The British Journal of Experimental Pathology Vol. XXVI No.4 August 1945;
 - (b) Clark et al; British Journal of Haematology 1999 106 834-826
 - (c) Solola et al; Obstetrics and Gynecology Vol. 61 No.1 January 1983
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terri L Ivory - McCaa whose telephone number is 703-605-1207. The examiner can normally be reached on M-F 8:30-4:30.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on 703-305-3399. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Terri McCaa
Patent Examiner
Art Unit 1641
April 23, 2001

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641